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10/533,842

05/04/2005

Ian Clarke

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/533,842 | Applicant(s) CLARKE ET AL. | |
| | Examiner Phil Wiest | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7,9-11,15,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7,9-11,15,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

In the reply filed 2/19/08, applicant amended claims 1 and 2. Claims 1, 2, 4, 7, 9-11, 15, 19, and 20 are currently pending.

Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pressure regulator, does not reasonably provide enablement for the pressure regulator self-regulating without direct pressure feedback from the liquid being dispensed from the flexible bag. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Paragraph [0040] of applicant's pre-grant publication does not adequately disclose that direct pressure feedback may not be used to control the pressure, nor does it disclose any benefits that such a system would have over one that utilizes direct pressure feedback.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4, 7, 10, 11, 19, and 20 have been considered but are moot in view of the new ground(s) of rejection.

In the interview held on 10/24/07, the examiner acknowledged that Laing does not teach regulating the pressure within the chamber without the use of direct feedback.

However, upon further inspection of the Keime reference, the examiner has determined that Keime provides ample motivation for pressure control without the use of direct feedback.

Applicant also argues that Keime does not suggest a pressure regulator that regulates at a constant and predetermined level. Applicant states that the desired pressure is overshoot by about 10 millibars then corrected during the pressure build up cycle. This argument has not been found persuasive. Even though the desired pressure is briefly overshoot, the pressure relief valve can quickly return the pressure to the desired level. Keime clearly suggests that the purpose of the pressure regulator and relief valve is to regulate the device at a constant and predetermined pressure. Just because the desired pressure is briefly overshoot during the build up cycle does not mean that the system is not regulated at a constant and predetermined pressure. Additionally, the automation of a manual activity does distinguish the claimed device from the prior art. Therefore it is the examiner's opinion that Keime clearly suggests the pressure regulation means claimed by applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 2, 4, 7, 9-11, 15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laing (CA 2,083,555) in view of Keime (GB 2,165,312).
2. With respect to Claims 1, 2, and 4, Laing discloses an apparatus 10 for controlled dispensing of a liquid from a flexible bag 40 comprising a chamber 20 adapted to contain the flexible bag 40, and an outlet (48 and 49) adapted to receive an outlet conduit 45 communicating with the flexible bag 40. A source of gas 58 is arranged to release gas into the chamber 20, applying pressure to the exterior walls of the flexible bag 40, and a pressure regulator 50 is operable to self-regulate the pressure applied to the bag throughout the dispensing process, thus causing fluid to be dispensed from the bag in a controlled manner. The pressure regulator 50 comprises a microprocessor 56, an air pump 58, and a transducer 55. Regarding Claim 2, the air bag portion 30 of the chamber 20 is substantially air tight. The outlet (48 and 49) comprises a clamp 28 and a needle 29 adapted to seal the chamber (Page 11, Lines 3-26), and the gas supply 58 is operable to supply gas under pressure to the interior of the chamber 20. The liquid outlet from the chamber is sealed to the outlet conduit in a way that effectively prevents liquid from leaking outside of the conduit. The pressure regulator 50, which comprises air pump 58, microprocessor 56, and pressure transducer 55, is arranged to regulate the flow of gas from the source to the chamber (Page 12, Lines 15-20). Laing, however, does not specifically disclose that the pressure regulator self-regulates the pressure without direct pressure feedback from the liquid being dispensed from the flexible bag.

Keime discloses a portable injector comprising a compressed gas source 18 that injects gas into a chamber to initiate fluid flow. The device further comprises a pressure

regulator 23 and pressure relief valve 22 that are capable of controlling the air pressure in the chamber. The pressure regulator is disposed at the inlet to the chamber, between the gas source and the flexible bag, and self regulates the pressure in the chamber without the need for direct pressure feedback. Although the desired pressure is initially overshoot by about 10 millibars, it is quickly stabilized to the desired pressure shortly thereafter. Although the regulator 23 is adapted for manual control, it is fully capable of being used to regulate the pressure within the chamber, and Keime clearly suggests that maintaining a specific pressure is the ultimate goal of the regulator see Page 2, Lines 30-85). The automation of a manual activity does not constitute a patentable improvement over the prior art. See MPEP § 2144.04 [Section III]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Laing with the pressure regulator and pressure relief valve of Keime in order to provide an alternate, direct feedbackless means for regulating the air pressure within the chamber.

3. With respect to Claims 4 and 19, Laing further discloses that the source of gas 58 is connected to an inflatable bladder 30 such that the inflatable bladder is in contact with at least a portion of the exterior wall of the air bag 40. See Figure 1. Regarding claim 19, the pressure regulator is operable to regulate the flow of gas from the source into the inflatable bladder (Page 7, Lines 14-26).

4. With respect to Claim 7, Laing discloses that the inflatable bladder 30 comprises an inflatable sock positioned and operable to wrap around at least a portion of the

flexible bag 40 (see Figure 1). An “inflatable sock” is interpreted by the examiner as being any type of bag that is capable of being filled with air.

5. With respect to Claims 10 and 11, Laing discloses that the source of gas is a reservoir 35 pressurized by a pump 58 (see Figure 1). The pump 58 is controlled by the microprocessor 56 in order to change the pressure in the inflatable bladder, thus controlling the flow rate of fluid from the flexible medical supply bag.

6. With respect to Claim 20, Laing discloses that the apparatus comprises a first chamber 10 comprising a flexible bag and a second chamber (50, 52) comprising the source of gas (air pump 58) and the pressure regulator 50.

7. With respect to Claim 9, Laing discloses the portable injector of claim 1 (see rejection above) wherein air is pumped into the chamber 30 by pump 58. Laing does not disclose that the source of gas comprises a pressure vessel of precompressed gas. Keime discloses a portable injector comprising a compressed gas source 18 that injects gas into a chamber to initiate fluid flow. The device further comprises a pressure regulator 23 that is capable of controlling the amount of air infused into the chamber, thus controlling fluid flow. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the portable injector of Laing with the pressurized gas source of Keime in order to provide an alternate means for pressurizing the chamber to create fluid flow from the bag. The use of pressurized gas sources to pressurize a chamber is well established in the art of fluid flow.

8. With respect to Claim 15, Laing discloses the portable injector of Claim 1 and that the chamber 10 has a depth significantly less than the length and width of the chamber (see Figure 1). Laing, however, does not disclose that the pressure vessel and pressure regulator are located alongside the chamber in a common housing. Keime discloses a portable injector wherein the pressure vessel 18 and pressure regulator (21, 23) are located alongside the chamber 4 in a common housing arranged in a cuboidal configuration such that the pressure vessel and pressure regulator are contained within the depth of the housing (see Figures 1 and 2). Repositioning the pressure vessel and regulator within the chamber housing will improve the portability of the device. Additionally, integration of components and changes of shape are mere matters of design choice and do not represent a patentable improvement over the prior art. See MPEP § 2144.04.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/

Application/Control Number: 10/533,842

Page 9

Art Unit: 3761

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761